SUMMARY REPORT
of the
NATIONAL BIODEFENSE SCIENCE BOARD
December 17–18, 2007
Ronald Reagan Building and International Trade Center
1300 Pennsylvania Avenue, NW
Washington, DC 20004

VOTING MEMBERS
Patricia Quinlisk, M.D., M.P.H., *Chair*
Ruth L. Berkelman, M.D.
Stephen V. Cantrill, M.D.
Roberta Carlin, M.S., J.D.
Albert J. Di Rienzo
Kenneth L. Dretchen, Ph.D.
John D. Grabenstein, R.Ph., Ph.D.
James J. James, Brigadier General (Retired), M.D., Dr.P.H., M.H.A.
Thomas J. MacVittie, Ph.D.
John S. Parker, Major General (Retired), M.D.
Andrew T. Pavia, M.D.
Eric A. Rose, M.D.
Patrick J. Scannon, M.D., Ph.D.

EX OFFICIO MEMBERS
(designee present, December 17)
Joseph Annelli, D.V.M., Animal and Plant Health Inspection Service, U.S. Department of Agriculture
Hugh Auchincloss, M.D., National Institute of Allergy and Infectious Diseases, National Institutes of Health, U.S. Department of Health and Human Services
Richard E. Besser, M.D., Coordinating Office for Terrorism Preparedness and Emergency Response, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services
Michelle M. Colby, D.V.M., M.S., Office of Science and Technology Policy, Executive Office of the President
Lawrence Deyton, M.D., M.S.P.H., Chief Public Health and Environmental Hazards, U.S. Department of Veterans Affairs
Bruce Gellin, M.D., M.P.H., National Vaccine Program Office, Office of the Secretary, Office of Public Health and Science, U.S. Department of Health and Human Services
Rosemary Hart, Office of Legal Counsel, U.S. Department of Justice
Maryanna Henkart, Ph.D., Directorate for Biological Sciences, National Science Foundation
Peter Jutro, Ph.D., National Homeland Security Research Center, U.S. Environmental Protection Agency
Lawrence (Larry) D. Kerr, Ph.D., National Counterproliferation Center, Office of the Director of National Intelligence

Carol D. Linden, Ph.D., Biomedical Advanced Research and Development Authority, Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services
Boris D. Lushniak, M.D., M.P.H., Rear Admiral/Assistant Surgeon General, Office of the Commissioner, Food and Drug Administration, U.S. Department of Health and Human Services
Willie May, Ph.D., National Institute of Standards and Technology, U.S. Department of Commerce (Dr. Michael Amos, designee)
Claudia A. McMurray, Ph.D., Environmental and Scientific Affairs, U.S. Department of State
Patricia A. Milligan, R.Ph., C.H.P., U.S. Nuclear Regulatory Commission
Donald L. Noah, D.V.M., M.P.H., Office of Health Affairs, U.S. Department of Homeland Security (Dr. Diane Berry, designee)
Timothy R. Petty, Deputy Assistant Secretary for Water and Science, U.S. Department of the Interior
John P. Skvorak, Colonel, D.V.M., Ph.D., U.S. Army Medical Research Institute for Infectious Diseases, U.S. Department of Defense
Ken Staley, M.D., M.P.A., Homeland Security Council, Executive Office of the President
Richard S. Williams, M.D., Office of the Chief Health and Medical Officer, National Aeronautics and Space Administration (Dr. David Liskowsky, designee)
Patricia R. Worthington, Ph.D., Office of Health and Safety, U.S. Department of Energy

EX OFFICIO MEMBERS - (designee present December 18)

Willie May, Ph.D., National Institute of Standards and Technology, U.S. Department of Commerce (Dr. Michael Amos, designee)
Claudia A. McMurray, Ph.D., Environmental and Scientific Affairs, U.S. Department of State (Dr. Jeff Miotke, designee)
Richard S. Williams, M.D., Office of the Chief Health and Medical Officer, National Aeronautics and Space Administration (Dr. David Liskowsky, designee)
Patricia R. Worthington, Ph.D., Office of Health and Safety, U.S. Department of Energy (Dr. Bonnie Richter, designee)

STAFF OF THE NATIONAL BIODEFENSE SCIENCE BOARD
Leigh Sawyer, D.V.M., M.P.H., CAPT, U.S.P.H.S., Executive Director
David Noll, Ph.D., Science Policy Fellow
Donald Malinowski, M.S., Program Analyst
Brook Stone, M.F.S., Program Analyst
Shirley Johnson, Executive Assistant

WELCOME
Leigh Sawyer, D.V.M., M.P.H., CAPT, U.S.P.H.S.

CAPT Sawyer, Executive Director of the National Biodefense Science Board (NBSB), welcomed the Board members and audience to the inaugural meeting of the NBSB. She explained that the mission of the Board is to provide expert advice and guidance to the Secretary of the Department of Health and Human Services (HHS) regarding current and future chemical, biological, nuclear, and radiological (CBRN) threats, whether naturally occurring, accidental, or deliberate. (The NBSB charter and the Federal statute establishing the NBSB appear on the Board's website at http://www.hhs.gov/aspr/omsph/nbsb/. Slides presented at the meeting are available by request to NBSBQuestions@hhs.gov.) CAPT Sawyer introduced RADM W. Craig Vanderwagen, M.D., the Assistant Secretary for Preparedness and Response since March 2007.

SWEARING-IN AND INTRODUCTION
Michael O. Leavitt, Secretary of Health and Human Services, HHS

Secretary Leavitt said that the events of September 11, 2001, led to the rebirth of a national emergency response plan, and Hurricane Katrina provided further lessons about what such a plan needed to address. Congress passed the Pandemic and All Hazards Preparedness Act (PAHPA) in 2007 to bolster emergency preparedness efforts that combine issues related to national security and defense with those of natural and accidental disasters. As a result of PAHPA, the Biomedical Advanced Research and Development Authority (BARDA) was created to facilitate research, development, and acquisition of countermeasures for serious health threats. In addition, PAHPA established the NBSB, which brings together the best minds in the field to offer their perspectives and contribute to the decision-making process. Secretary Leavitt anticipated harnessing the collective expertise of the NBSB to help HHS make the best possible decisions. Secretary Leavitt then swore in the 13 voting Board members.

OVERVIEW OF AGENDA
RADM W. Craig Vanderwagen, M.D., Assistant Secretary for Preparedness and Response, HHS

RADM Vanderwagen thanked the Board members for being willing to work as a team and gave an overview of the agenda for the meeting. He noted that the Office of the Assistant Secretary for Preparedness and Response (ASPR) is working in partnership with the White House, which has high expectations for the NBSB. He introduced Robert P. Kadlec, M.D., noting that as an aide to Senator Richard Burr, Dr. Kadlec contributed substantially to PAHPA and brings much expertise to his new position as Special Assistant to the President for Homeland Security and Senior Director for Biological Defense Policy.

REMARKS
Robert P. Kadlec, M.D., Special Assistant to the President for Homeland Security; Senior Director for Biological Defense Policy

Dr. Kadlec said that Congress engaged in a truly bipartisan effort to pass PAHPA, which is intended to reorganize the national infrastructure to better prepare the nation for emergencies. In the 20th century, defense efforts focused on nuclear threats. In the 21st century, they must focus on biological threats. The NBSB brings together experts from around the country to help the Federal government address operational and tactical issues. Dr. Kadlec emphasized that while there has been no attack on the U.S. homeland since 2001, the country remains at war against a relentless and vicious enemy that has demonstrated it will use its weapons against innocent people. He looked forward to the NBSB's assistance in helping to ensure the public health and security of the nation.

CHALLENGES AND OPPORTUNITIES IN BIODEFENSE
RADM W. Craig Vanderwagen, M.D., Assistant Secretary for Preparedness and Response, HHS

RADM Vanderwagen introduced the morning's speakers as the senior-most leaders in public health and medicine from across the Federal government. He emphasized that while the Federal government is moving forward on emergency preparedness and response with a sense of urgency, the Board members should not let that inhibit them from addressing the long-term challenges of biodefense. He asked the Board members to consider the underlying theme of all the presentations: the need to align thinking to address policy and tactical needs to meet the requirements of biodefense. He explained that the biodefense enterprise includes everything from initial research through development to deployment of countermeasures where they are most needed. No single Federal entity controls the biodefense enterprise; rather, Federal entities must work together to identify the best ideas, facilitate research and development, and make countermeasures accessible and available. Board members should consider the whole enterprise, from research to deployment, and offer innovative ideas that reflect the needs of their own communities.

Anthony S. Fauci, M.D., Director, National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), HHS

Dr. Fauci emphasized that the NIH's primary roles in public health preparedness are to conduct basic and clinical research to develop medical interventions (e.g., diagnostic tools, therapeutics, and vaccines) and to build the intellectual infrastructure on which future research and development depends. The NIH maintains an ongoing matrix of research but also must respond quickly to new public health threats with expedited research efforts, as it did in response to HIV/AIDS and West Nile virus. Dr. Fauci noted that the NIH's investment in infrastructure to address emerging and re-emerging infectious diseases puts it in good stead to address CBRN threats, pointing to advances in countermeasures for smallpox, anthrax, Ebola, and influenza (flu). The NIH has established eight Centers for Medical Countermeasures against Radiation and the Countermeasures against Chemical

Threats program, as well as partnerships and agreements to support research and product development. The NIH's research agendas and strategic plans are available online.

Andrew von Eschenbach, M.D., Commissioner, Food and Drug Administration (FDA), HHS

Dr. von Eschenbach stressed the importance of science and technology in protecting the health and welfare of the public, whether the threat is intentional or unintentional, chemical or biological. He explained that the FDA recognizes that regardless of the source of the threat, be it intentional contamination of food with biologic or chemical agents or unintentional contamination from *Escherichia coli*, for example, the response must be unified and seamless. The FDA has focused on increasing coordination among its various divisions, and those lessons will come into play in addressing biodefense across Federal agencies. The FDA should be a bridge, not a barrier, to ensure that interventions are available to populations in need, Dr. von Eschenbach said. In the 21st century, the FDA will improve the regulatory process by applying science and technology to make appropriate decisions, irrespective of other influences.

Among the tools FDA can use to speed its ability to make products available are the processes of emergency use authority, priority review, fast-track review, and the so-called animal efficacy rule, which allows FDA to extrapolate data from animal testing to assess efficacy of drugs intended for humans. Dr. von Eschenbach added that the FDA hopes to be more involved in the front end by providing guidance and consulting with industry during the development and testing phases. He said the FDA has been able to foster manufacturing and approval processes that streamlined the development of a pandemic flu vaccine, for example. The FDA has mechanisms, processes, and commitments in place to continuously improve through collaboration and cooperation with bodies such as the NBSB and other Federal agencies.

Julie Gerberding, M.D., M.P.H., Director, Centers for Disease Control and Prevention (CDC), HHS

Dr. Gerberding said the 9/11 attacks made clear the need for HHS leadership to work together across agencies. Since that time, the country has faced not only the destruction of the World Trade Centers and the threat of anthrax, but also the severe acute respiratory syndrome (SARS) virus and monkeypox, hurricanes, a vaccine recall, a particularly serious flu season, and more. Dr. Gerberding said the threats are larger and coming faster, and the nation has come to expect instant—and effective—responses from its public health system. She emphasized that in this setting, work must be done "at the speed of the Internet, not the speed of government." In short, the environment demands solutions that are cheaper, better, and faster than ever.

Dr. Gerberding said the CDC has gone beyond buying supplies and warehousing them, moving into innovative health care delivery approaches that provide protection equitably across communities in need. For example, the CDC pilot-tested the action of delivering

medical countermeasures (in the form of antibiotics) to homes by mail and through private businesses such as Wal-Mart.

In addition to seeking out new solutions, Dr. Gerberding asked the Board to address the complacency among the public that has developed in the 6 years since the terrorist attack on the homeland. In both efforts, she encouraged Board members to speak up, either individually or as a body.

CHAIR'S REMARKS AND BOARD MISSION AND GOALS
Patricia Quinlisk, M.D., M.P.H.

Dr. Quinlisk thanked the presenters and Secretary Leavitt, saying their presence demonstrates the importance of the Board to their agencies. She reiterated the mission of the Board and noted that while the scope of the mission is broad, she hoped the Board would strive to give practical, useful, and timely advice to the Secretary. She stressed the need to ensure public input into the deliberation process. The goal of the inaugural meeting, Dr. Quinlisk said, is to consider some topics of interest presented by HHS that the Board may wish to address and identify other issues Board members feel should be considered.

Dr. Quinlisk said the Board members bring to the table an amazing amount of experience, knowledge, and expertise. She described her own background and experience and invited each Board member to do the same. Biographies of all voting Board members are available on the Board's website (http://www.hhs.gov/aspr/omsph/nbsb/).

NBSB STRUCTURE AND OPERATIONS
Leigh Sawyer, D.V.M., M.P.H., CAPT, U.S.P.H.S., Executive Director, NBSB, ASPR, HHS

CAPT Sawyer reviewed the conflict of interest guidelines that govern Federal advisory boards. Under the Federal Advisory Committee Act (FACA), members of bodies such as NBSB are considered special government employees and are subject to the laws, regulations, and standards of ethical conduct that apply to employees of the executive branch. In reporting possible conflicts of interest before each NBSB meeting, members should be sensitive to both real and perceived conflicts. CAPT Sawyer performed the official roll call for the meeting and introduced the NBSB staff members.

U.S. GOVERNMENT POLICIES ON PREPAREDNESS AND RESPONSE
BIODEFENSE UPDATE: FROM POLICY TO PRACTICE
Brian Kamoie, M.P.H., J.D., Deputy Assistant Secretary for Preparedness and Response; Director, Office of Policy, Strategic Planning, and Communications, ASPR, HHS

Mr. Kamoie explained that PAHPA, which established the ASPR, requires the Secretary to present a National Health Security Strategy by 2009 and every 4 years thereafter. Three

Homeland Security Presidential Directives (HSPDs) also guide the activities of the ASPR. *Biodefense for the 21st Century*, HSPD-10, describes the four pillars of the national biodefense program: threat awareness, prevention and protection, surveillance and detection, and response and recovery. *Medical Countermeasures against Weapons of Mass Destruction*, HSPD-18, encourages investment of resources in developing countermeasures against those threat agents with the greatest potential for use. It also emphasizes the need for effective, realistic deployment strategies. Mr. Kamoie said the strategic plan being drafted by BARDA addresses medical countermeasures but would benefit from input by the Board and others, particularly on implementation issues.

Public Health and Medical Preparedness, HSPD-21, builds on the 2002 National Strategy to Combat Weapons of Mass Destruction and the 2007 National Strategy for Homeland Security and complements PAHPA. It emphasizes the importance of involving State and local partners in preparedness, including nongovernmental entities, individuals, and communities. Mr. Kamoie noted that the Board can play a key role in national planning and preparedness efforts by providing real-world input on translating policy into practice.

OVERVIEW OF THE U.S. GOVERNMENT PREPAREDNESS AND RESPONSE ACTIVITIES FOR NATIONAL INCIDENCES

VADM Harvey Johnson (U.S. Coast Guard, Retired), Deputy Administrator, Federal Emergency Management Agency (FEMA), U.S. Department of Homeland Security (DHS)

VADM Johnson explained how the National Response Framework (NRF) differs from the National Response Plan. As a national—not Federal—approach, the NRF emphasizes the dominant role of States in responding to disasters with Federal support and assistance. Because private entities own 85 percent of the country's key infrastructure, they must also be engaged in preparedness efforts. The NRF describes the key roles and responsibilities of the Federal government, States, and private entities in response to all types of hazards. The key differences between the NRF and the National Response Plan, which was released just before Hurricane Katrina occurred, are as follows:

- Focuses exclusively on immediate response, with anticipation that guidelines on prevention, protection, and long-term recovery are forthcoming
- Targets executive-level readership with shorter text and provides links to online resources and information that individuals at all levels can use for implementation
- Outlines a "response doctrine," which emphasizes a tiered response approach that encourages communities at each level to anticipate when higher-level resources are needed, advocates cooperation and collaboration among entities according to capacity and resources, and stresses readiness
- Explains the planning process in detail and encourages use of common terminology across the country

VADM Johnson noted that the FEMA will require States and territories to incorporate relevant elements of the NRF in their Federally funded efforts. For example, to receive an emergency medical grant, applications must address emergency evacuation and sheltering

for people with special needs. Mr. Kamoie added that HHS also factors NRF benchmarks into its grantmaking and will align its funding with DHS requirements wherever possible.

OVERVIEW OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES' PREPAREDNESS AND RESPONSE ACTIVITIES FOR PUBLIC HEALTH AND MEDICAL EMERGENCIES

Kevin Yeskey, M.D., Director, Office of Preparedness and Emergency Operations (OPEO), ASPR, HHS

Dr. Yeskey said the mission of the OPEO is to lead the nation in preventing, preparing for, and responding to the adverse health effects of public health emergencies and disasters, ensuring "that people have the right stuff at the right time and in the right way" to respond appropriately. For example, the OPEO has developed playbooks that look at the immediate response needs for a disaster scenario, identify gaps, and describe key lessons learned. The OPEO is also working with the National Library of Medicine on an interactive computer program to help clinicians manage victims of "dirty" bombs. It is engaged with FEMA on gap analysis, e.g., how well hospitals are equipped to shelter their patients in place or evacuate them. The OPEO is collaborating with the Red Cross on tools to triage people with special needs to determine which individuals can function in an ordinary shelter for evacuees and which need special settings. With the Agency for Healthcare Research and Quality, it has published guidelines on allocating scarce resources and a handbook on how health care providers can work across boundaries to provide emergency aid.

Dr. Yeskey said the OPEO is also focusing on integrating public health emergency response efforts at every level. It is providing technical assistance to States and localities to better coordinate patient treatment, transfer, and tracking. Overall, the OPEO seeks to provide more and better information to enable appropriate emergency response.

ISSUES AND TOPICS FOR NBSB CONSIDERATION (PART I)

Patricia Quinlisk, M.D., M.P.H.

Dr. Quinlisk asked Board members to identify any topics of particular interest that were not covered in the five topics for consideration identified by the NBSB staff (which presenters would address in detail).

TRAINING AND EDUCATION

Dr. Cantrill suggested expansion of emergency response training for health care providers and beyond those directly involved in emergency management.

Dr. John Parker felt the NRF should address emergency preparedness for the whole nation, not just emergency management.

Dr. Quinlisk suggested development of mechanisms for learning from real-life emergency response situations.

CURRENT EFFORTS AND RESOURCES

Dr. Dretchen recommended evaluating biosurveillance efforts under way at all levels to determine existing, proposed, or needed coordination of such efforts.

Dr. Berkelman suggested raising awareness about the profound disparities in the structure, capacity, and competencies of local, community, and State public health response systems, as well as developing guidance derived from model systems.

Ms. Carlin recommended developing a resource clearinghouse or other mechanisms to reduce duplication of efforts and fragmentation of resources.

NEW EFFORTS

Dr. Rose suggested looking at ways to optimize delivery systems when innovative distribution models are in place.

Dr. James recommended developing definitions and a common terminology.

Dr. James also suggested developing a lifecycle model that begins with training and educating personnel and developing systems to support their needs.

Mr. Di Rienzo recommended identifying thresholds of response, prevention, etc., that trigger the need for a higher-level (higher tier) response.

COMMUNICATION

Dr. John Parker suggested encouraging individual citizens to 1) understand their role in preparedness and response, 2) identify what they need to be better prepared, and 3) communicate their needs.

INTRODUCTION AND DISCUSSION OF PROPOSED TOPICS

In advance of the meeting, Board members received from NBSB staff five topics for potential consideration, each with a brief background discussion. At the meeting, presenters elaborated on the five proposed topics.

EVALUATING RESEARCH AND DEVELOPMENT COMPONENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES' INFLUENZA PREPAREDNESS STRATEGY

Robin Robinson, Ph.D., Deputy Director, BARDA, ASPR, HHS

Dr. Robinson emphasized that efforts to address pandemic flu are inextricably linked with seasonal flu and national concerns cannot be divorced from international responsibilities. He hoped the Board would call on a workgroup of scientists, public health officials, and others to help it guide decision-making about some specific research questions, such as the following:

- Can the longevity of the stockpile of pandemic or seasonal vaccines be increased? When does a vaccine go bad?
- Is it possible to create a pre-pandemic vaccine that prepares the body for administration of a pandemic vaccine or adjuvants to seasonal vaccines that act as a pandemic vaccine?
- Can antivirals be combined with flu vaccines? Can the public health system manage an outbreak by using antiviral prophylaxis? If so, how would responsibility for such an effort be shared?
- Can therapeutic antibodies be used to manage an outbreak? Are data from the NIH on this issue sufficient to move forward?
- Can better diagnostic methods be developed for clinicians?
- How can training be targeted beyond those who administer flu vaccine to others involved in emergency preparedness?

Dr. Robinson noted that these are among the top questions being considered by BARDA and the CDC, and BARDA seeks input from the Board on fine-tuning its research questions to incorporate real-world priorities and challenges. He also hoped Board members will help communicate with their colleagues about BARDA's research efforts.

SUPPORTING MEDICAL COUNTERMEASURE DEVELOPMENT THROUGH INNOVATION
Michael Callahan M.D., D.T.M.&H. (U.K.), M.S.P.H., Program Manager, Accelerated Manufacture of Pharmaceuticals, Defense Sciences Office, Defense Advanced Research Projects Agency (DARPA), Department of Defense (DOD)

Dr. Callahan said the DARPA seeks to encourage innovation by not only speeding up the development process for medical countermeasures but also broadening the scope and preserving and leveraging existing assets. At the Federal level, much innovation occurs at the NIAID, and discoveries are distributed across the NIH landscape and out to other agencies. The military's most mature program for developing medical countermeasures is the Defense Threat Reduction Agency, which is driven by specific requirements, such as those of soldiers at war. The DARPA brings together experts from various fields to embark on proof of concept. Beyond the issues of speedy development, cost, and FDA approval, the DARPA looks at practical matters of distribution and technologies that can optimize production. The DARPA seeks to invest in rapid, agile technology that complies with good manufacturing practices.

Dr. Callahan emphasized that the DARPA strives to facilitate communication among stakeholders and to bring together the right people to create an atmosphere that fosters innovation. He said the Board could be of assistance in educating academia and industry about the need for strategic planning and the potential for cooperation with the Federal government.

ADDRESSING GAPS IN THE MEDICAL COUNTERMEASURES MARKETPLACE
Richard J. Hatchett, M.D., Associate Director for Radiation Countermeasures Research and Emergency Preparedness, NIAID, NIH, HHS

The development of medical countermeasures is hampered by high cost and limited markets. Federal biodefense efforts have sought to provide incentives to spur such development, but those efforts have been piecemeal, Dr. Hatchett noted, and regulatory protections and exclusivity agreements have had limited success. Incentives work by influencing behavior in an established market; they have yet to succeed in promoting development in the biodefense market. He believes efforts to date have not focused on what motivates the private sector.

For example, makers of pharmaceuticals and biologicals are seeking to develop products for definable, long-lasting markets that provide a reasonable return on investment. Dr. Hatchett pointed out that the path from clinical research to market is long, complicated, and unpredictable. From an industry perspective, the government's approach to purchasing and stockpiling—i.e., a centralized method that minimizes acquisitions and is replenished as needed—may be a disincentive to private-sector development of medical countermeasures.

Dr. Hatchett asked the Board to consider market-related questions, such as whether a product that functions only as a medical countermeasure has sufficient market value to a private-sector manufacturer and whether the potential market for countermeasures among nongovernment, private entities (e.g., corporations that stockpile Tamiflu® [oseltamivir phosphate] for their workers) influences industry decision-making. Dr. Grabenstein added that in many industries, the initial investment in creating a new product is the largest expense. Dr. Dretchen noted that the government's practice of purchasing exclusively from one vendor may create a disincentive to other manufacturers.

MODELING AND METRICS TO INFORM MEDICAL CONSEQUENCE ASSESSMENT
Peter Highnam, Ph.D., Senior Advisor, Modeling and Information Technology, BARDA, ASPR, HHS

Dr. Highnam described the essential role that modeling has in exploring the potential consequences of, and responses to, public health events for which there is no significant modern experience. Modeling, simulation and other analytic approaches must be used to support decision-makers. Substantial input from all stakeholders is required. Dr. Highnam presented several questions for consideration by the Board, such as the following:

- How can modeling best support policy, procurement, and operational decision-makers in the face of diverse public health threats of undetermined frequency and scale?
- Investments in all aspects of detection, response and recovery yield benefits in terms of medical consequences. How should we help decision-makers explore their options and the trade-offs, across organizations?
- How do we capture and use on-the-ground clinical realities in medical consequence assessment for large-scale events?

- What are appropriate metrics and models to use to track and predict real-time progress and effectiveness in the use of countermeasures during a pandemic or CBRN event?
- Given U.S. population demographics, how do we ensure investigation of medical consequences in subpopulations?
- Is there appropriate behavioral modeling for estimating population responses to an event, and to information that is disseminated (official and otherwise) for that event?
- Which communities should be tapped for expertise, tools and data? Are there existing communities (ex. DoD) that can provide appropriate analysis tools for civilian events?
- Is there a role for modeling to support medical countermeasure decision-making transparency in the presence of adversaries?

SPECIAL AND AT-RISK POPULATIONS—CONSIDERATIONS FOR MEDICAL COUNTERMEASURE RESEARCH, DEVELOPMENT, AND DEPLOYMENT PLANS

Dan Dodgen, Ph.D., Director, Office of At-Risk Individuals, Behavioral Health, and Human Services Coordination, OPEO, ASPR, HHS

Dr. Dodgen noted that PAHPA defines at-risk individuals as children, pregnant women, senior citizens, and others with special needs in the event of a public health emergency. The statute requires these individuals be included in the National Health Security Strategy, planning for the Strategic National Stockpile, any public health emergency efforts that identify children as a priority, curricula and training efforts related to all-hazards public health and medical response, and the functions of BARDA. Because the statutory definition covers such a broad range of populations, HHS is applying a working definition that identifies functional barriers, such as disability, chronic medical conditions, and cultural or language barriers. The HHS' working definition also includes people with pharmacological dependency, intended to address populations being treated for substance abuse problems, such as methadone users.

Dr. Dodgen said that if the Board were to address the topic of special and at-risk populations, it could be very helpful in identifying the unique considerations required to assist various types of at-risk individuals in specific, real-world situations. He noted that in terms of providing a basic need—e.g., emergency evacuation and shelter—the definition of at-risk individuals could include 50–60 percent of the population. Communicating effectively with at-risk individuals during a public health emergency is one of many significant concerns that should be addressed. The HHS seeks the Board's input on deploying countermeasures for people at risk in an effective manner.

GENERAL DISCUSSION AND QUESTIONS FROM THE BOARD

Dr. Quinlisk asked the presenters to define "countermeasures." Most said they were referring to medical diagnostic and therapeutic approaches to treat disease and mitigate its spread, including nonpharmaceutical measures (e.g., face masks and respirators), but some also included nonmedical approaches, such as social distancing.

CAPT Sawyer noted that the Board should determine not only the topics it would like to address but also its methodology. Dr. Quinlisk said the five topics suggested by NBSB staff represented the priorities of HHS but that should not limit the Board from bringing its members' experience and expertise to bear on topics of its own choosing.

Dr. James stressed the need for the Board to determine its scope of work and maintain its focus. Dr. Pavia suggested the Board limit its choices to topics that require immediate input and in which the Board can have significant influence. Dr. Quinlisk added that the Board should develop both short- and long-term goals. Mr. Di Rienzo felt the Board should create a roadmap, and Dr. James noted that HSPD-21, *Public Health and Medical Preparedness*, offers a roadmap for an integrated Federal response that the Board should take into account.

THE HHS PUBLIC HEALTH EMERGENCY MEDICAL COUNTERMEASURE ENTERPRISE

OVERVIEW OF THE PUBLIC HEALTH EMERGENCY MEDICAL COUNTERMEASURE ENTERPRISE

Gerald W. Parker, D.V.M., Ph.D., M.S., Principal Deputy Assistant Secretary for Preparedness and Response, HHS

Dr. Gerald Parker noted that the 9/11 attacks and hurricanes Katrina, Rita, and Wilma underscored the need to improve decision-making and transparency in emergency preparedness, particularly coordination of efforts among government entities at all levels and community and private-sector partners. As a result, in July 2006, HHS transformed a subcommittee that had been tasked with addressing the public health consequences of weapons of mass destruction into the Public Health Emergency Medical Countermeasure Enterprise (PHEMCE): an interagency effort under the ASPR that includes leaders from CDC, NIH, and FDA as well as input from the departments of Defense, Homeland Security, Veterans Affairs, and State, among others. The PHEMCE aims to define and prioritize public health medical countermeasures; align research, development, and procurement efforts around its priorities; and establish strategies to deploy medical countermeasures in the Strategic National Stockpile. The PHEMCE has succeeded in gaining consensus among its voting members and advising the Secretary on strategic approaches.

The PHEMCE's efforts would be bolstered by a better understanding of the priorities of communities during public health emergencies. It has convened meetings with stakeholders and published strategic and implementation plans that identify priorities and reasonably achievable goals given funding available through Project BioShield.

In addition, PHEMCE is encouraging research that identifies emerging threats, and BARDA can aid in that respect by translating laboratory research on threats into useful medical countermeasures. Dr. Gerald Parker emphasized that the Board's input on moving BARDA efforts forward would be valuable.

Dr. Gerald Parker said the public must have confidence that medical countermeasures are safe and effective. Because there are few models to guide research, development, regulation, and distribution of medical countermeasures, the PHEMCE is open to bold new ideas from the Board and others. In addition, PHEMCE seeks input on how to recruit experts beyond the Federal government—at State and local levels and from private industry and professional organizations—to assist in development and deployment of medical countermeasures.

RESEARCH AND DEVELOPMENT
Michael G. Kurilla, M.D., Ph.D., Director, Office of BioDefense Research Affairs; Associate Director for BioDefense Product Development, NIAID, NIH, HHS

Dr. Kurilla described the path of product development, from the basic and applied research conducted at NIH and elsewhere to advanced product development (such as BARDA's efforts), FDA approval, and distribution. Some recent initiatives by the Federal government seek to spur product development by providing services or mechanisms to fill the gaps in the product pathway, such as funding pilot-lot production or the development of animal efficacy models. Dr. Kurilla noted that NIAID updated its strategic plan for biodefense research in 2007, and the new version articulates the NIH's role in achieving the goals outlined in HSPD-18.

Dr. Kurilla explained that NIAID seeks not only to advance the development of new products for biodefense, but also to enhance existing products and improve methods for creating products. The NIH is also fostering more research on radiological and nuclear countermeasures, for example, by establishing eight Centers for Medical Countermeasures against Radiation.

ADVANCED DEVELOPMENT AND ACQUISITION PROGRAMS
Carol Linden, Ph.D., Acting Director and Deputy Director, BARDA, ASPR, HHS

Dr. Linden outlined BARDA's four-step approach to meeting its responsibilities:

1. Identify and assess threats using DHS' published material threat determinations.
2. Evaluate the potential medical and public health consequences of threats through modeling.
3. Prioritize medical countermeasure requirements, taking into account the availability of countermeasures and the need for new products.
4. Develop short- and medium-term strategies that focus on acquiring available products to address known threats using current funding and devise long-term strategies for developing countermeasures that take a broader approach to biodefense, such as use of broad-spectrum antivirals.

Project BioShield, established in 2004, enabled HHS to acquire medical countermeasures for CBRN threats, authorized NIH to revise its procedures for reviewing proposals and establishing contracts to facilitate research and development in this area, and allowed FDA to establish emergency-use guidelines for new products. Dr. Linden described several

products and research efforts fostered by Project BioShield. She added that BARDA is investing in infrastructure to support research on a pandemic flu vaccine in the United States and offers aid to other countries involved in such efforts.

The BARDA strategic plan emphasizes integration across the spectrum to facilitate research, development, and acquisition of medical countermeasures, including seeking a common research terminology. To achieve its goals, BARDA must create incentives for sustained research and development, understand marketplace challenges, recognize technical and regulatory barriers, address stockpiling and storage issues, and consider emergency deployment challenges.

APPROVAL AND LICENSURE OF MEDICAL COUNTERMEASURES

RADM Boris D. Lushniak, M.D., M.P.H., Assistant Commissioner, and CDR Carmen Maher, Policy Analyst, Office of Counterterrorism & Emerging Threats, FDA, HHS

RADM Lushniak stated that while some may view the FDA as an obstacle to product development, he sees the agency as providing regulatory pathways with milestones that demonstrate progress through the system and occasional hurdles that should be overcome to ensure product safety and efficacy. As a voting member of the PHEMCE, FDA provides technical and regulatory assistance and advice but does not vote on contract awards.

As Dr. von Eschenbach noted, the FDA seeks to work with product developers and the scientific community early in the process to ensure they understand FDA regulations for approval, such as data collection and analysis requirements. Its critical path initiative aims to speed product development while ensuring that product safety, medical utility, and manufacturing procedures are appropriately addressed. The animal efficacy rule allows product developers to provide data on the efficacy of drugs and biologics (but not devices) from validated animal studies when human studies are not possible or ethical, although safety data must still come from human studies.

CDR Maher said that while FDA had mechanisms in place to allow emergency use of unapproved products in individual patients or treatment protocols, Project BioShield enabled FDA to authorize emergency use of investigational medical countermeasures not yet approved in the event of an emergency declared by HHS. She cautioned that the FDA cannot "pre-authorize" emergency use, but it can collect and review data in advance that could contribute to decision-making in an emergency. Several conditions apply to emergency use authorization, and FDA can place restrictions on emergency use, as appropriate, based on the totality of available product data and the circumstances of the emergency.

PUBLIC HEALTH PREPAREDNESS, STOCKPILING, AND DEPLOYMENT

Richard E. Besser, M.D., Director, Coordinating Office for Terrorism Preparedness and Emergency Response, CDC, HHS

Dr. Besser noted that the CDC covers a wide range of scientific fields, such as epidemiology, laboratory science, countermeasure development, and pharmacology, and will readily identify experts to provide specific input to the Board on request. The CDC oversees the Strategic National Stockpile, from purchasing to maintenance and replacement, as well as deployment, distribution, and dispensing of countermeasures. Among its many responsibilities, the agency provides technical assistance to State and local health departments to build capacity and share best practices. The CDC seeks assistance from the Board and others in forging additional links with the public.

Dr. Besser stressed that considerations about product development should take into account the systems needed to ensure that individuals can receive the product, as well as how to evaluate and measure the effectiveness of such systems. He elaborated on the pilot project to assess the feasibility of home storage of specialized emergency antibiotic kits, mentioned by Dr. Gerberding. The project found that more than 95 percent of households properly stored and maintained the drugs, and more than 90 percent would like to have such emergency medicine kits in their homes.

GENERAL DISCUSSION AND QUESTIONS FROM THE BOARD

Dr. Cantrill asked whether the PHEMCE covered explosives and took into account primary blast injuries. Dr. Gerald Parker replied that explosives in general fall under the purview of the DHS, but medical countermeasures and some components of the Strategic National Stockpile include supplies for treating burns and trauma.

Dr. Scannon asked what mechanisms exist to ensure that information feeds into the basic research being conducted. Dr. Gerald Parker agreed that input from individuals and communities is needed to inform basic research. Dr. Besser noted that PAHPA requires annual assessment of the Strategic National Stockpile, which allows the Federal government to apply findings from new models and determine what's no longer needed. Dr. Linden said one advantage of the PHEMCE is the opportunity to gather input from various agencies.

Dr. Dretchen asked whether industrial chemicals were considered chemical threat agents. Dr. Gerald Parker responded that the phrase "all hazards" is intended to cover a wide range of threats, and under new guidelines industrial chemicals and wildfires, for example, would be part of disaster planning efforts.

Mr. Di Rienzo suggested the FDA educate the industry about how the FDA can provide assistance to facilitate product development. He asked whether the animal efficacy rule should be revised to cover devices, such as biofilms. RADM Lushniak said the FDA cannot modify the rule at present, but such considerations are looming. He added that the FDA's reviewers are already behind in their work and user fees do not cover pre-approval

consultations, so it is difficult for FDA to work with industry in the early stages of product development as much as it would like.

Dr. Rose asked whether emerging threats have been prioritized and expressed concern that publishing lists of emerging threats may expose vulnerabilities. Dr. Gerald Parker acknowledged the concern but noted that the prioritization of threats has changed little in the past 10 years. He said the best approach is to prepare for the known threats and focus on those, particularly anthrax. Dr. Gerald Parker emphasized that lessons learned from battling the seasonal flu virus can be applied to biodefense efforts.

Dr. John Parker asked how the Board could assist in filling in gaps identified by HHS, and Dr. Pavia requested elaboration on how the Board can help HHS with better decision-making and increased transparency. In response to both, Dr. Gerald Parker reiterated that the expertise of the Board's members will help inform the PHEMCE and that Board members can educate their colleagues and communities about Federal efforts toward emergency preparedness and medical countermeasures.

Ms. Carlin asked the presenters to keep special populations and at-risk individuals in mind as they develop exercises, drills, and distribution models. She added that her organization hopes to create better links between government agencies and people with disabilities.

THE HHS PANDEMIC INFLUENZA PROGRAM

OVERVIEW OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES' PANDEMIC INFLUENZA PLAN

Bruce Gellin, M.D., M.P.H., Director, National Vaccine Program Office, Office of Public Health and Science, HHS

Dr. Gellin updated the Board on the National Strategy for Pandemic Influenza, which describes efforts on preparedness, surveillance, containment, and shared responsibility among stakeholders from the global to the community level. Planning efforts have established five categories of severity (as with hurricanes), and responses would be situation-dependent. In determining what constitutes success, Dr. Gellin noted that mitigation of the impact of a pandemic virus within a community—for example, by staying at home or post-exposure prophylaxis—could reduce overall deaths significantly.

The Federal government is focusing on increasing manufacturing capacity for pandemic flu vaccine. The possibility of storing flu vaccine has become more feasible in recent years as researchers consider whether vaccines can provide partial protection in some cases and whether adjuvants can be used to close the gaps. The United States engages in international efforts to address pandemic flu through Ambassador John E. Lange, Special Representative on Avian and Pandemic Influenza, "the flu ambassador."

Dr. Gellin emphasized the importance of talking about who should receive a vaccine during an epidemic when supplies are limited. He stressed that, in making such determinations, communities are more likely to focus on their shared values to craft priorities than on calculations about potential outcomes. Dr. Gellin added that other Federal advisory

committees are addressing issues of prioritization, such as the DHS' National Infrastructure Council, and recommended communication among committees. He requested input from Board members on a proposed five-tiered list for pandemic vaccination allocation during a severe pandemic outbreak. Efforts to use communication tools to mitigate potential panic during an outbreak include the cross-agency website www.pandemicflu.gov.

PANDEMIC PREPAREDNESS AND RESPONSE ACTIVITIES
Robin Robinson, Ph.D., Deputy Director, BARDA, ASPR, HHS

Dr. Robinson said BARDA uses the HHS strategic plan to determine concrete goals, such as producing and stockpiling sufficient vaccine to protect a large portion of the workforce and to reduce the need to prioritize who receives the vaccine, developing effective diagnostic tools for use at home or at the point of care, and acquiring sufficient stock of other countermeasures, such as masks. The Federal government's pandemic flu medical countermeasures program emphasizes integration and collaboration across agencies. It encourages advanced product development and modernization of manufacturing processes.

GENERAL DISCUSSION AND QUESTIONS FROM THE BOARD

Ambassador Lange pointed out that HHS and the DHS work closely to address the potential threat of a domestic flu outbreak, while the State Department focuses on the international threat. The threat comes from both the possible spread of avian flu, which has already hit 60 countries, and pandemic flu. Ambassador Lange said a record number of governments were represented at a recent international conference that sought to broaden cooperation in dealing with the flu threat.

Dr. John Parker asked about the status of reporting on human and animal cases of avian flu and whether the current staging method is sufficiently detailed. Ambassador Lange responded that most governments have been forthcoming in reporting; the World Health Organization (WHO) is working with Indonesia, which is the only country deliberately withholding information. A few countries have reported cases of H5N1 virus in humans but not in poultry. Ambassador Lange says national health departments may be more willing to provide information than agricultural departments. He said there has been no discussion about refining the staging.

Dr. Scannon asked whether a vaccine might be sent overseas if an outbreak occurred outside the United States to prevent its migration to the United States. Ambassador Lange replied that it would take about 6 months to develop and produce a vaccine in the case of an outbreak, which would not be enough time to prevent spread to the United States. However, rapid response is a high priority, and efforts to delay the spread of disease are being considered. For example, the United States has pre-deployed a stockpile of countermeasures overseas. Dr. Gellin added that consideration is being given to a WHO stockpile as a potential tool in rapid containment efforts.

ISSUES AND TOPICS FOR NBSB CONSIDERATION (PART II)
Patricia Quinlisk, M.D., M.P.H., Chair

Dr. Quinlisk said the goal for the remainder of the meeting was to identify high-priority topics that the Board wished to address through subcommittees before its next meeting in approximately six months and to establish the needed subcommittees and points of contact for each. The presenters who addressed the five topics suggested by NBSB were on hand to answer questions.

Mr. Di Rienzo asked whether a noninvasive method for rapidly screening people entering the country would be of value in developing models to predict the spread of disease. Dr. Gellin replied that the pandemic flu severity index will rely on early predictors, so such a technique would be useful.

Dr. Cantrill asked what research was being done to examine the shelf life of drugs in State, national, and institutional stockpiles, given that little money is available to replenish stockpiles when drugs expire. RADM Lushniak responded that shelf life is strongly affected by storage conditions, and there are no guidelines for monitoring State, national, and institutional stockpile storage conditions. The FDA relies on manufacturer's data to propose a maximum shelf life. Currently, despite the potential waste of resources, FDA cannot extend shelf-life beyond a manufacturer's specified expiration date...without additional data from the sponsor or in some circumstances as part of the DOD's Shelf Life Extension Program. Dr. Dretchen said in a national emergency, the Federal government could test the viability of expiring drugs and enhance storage conditions to maximize the stockpile. RADM Lushniak responded that shelf life is strongly affected by storage conditions, and there are no guidelines for monitoring those. He added that the possibility that the Federal government might extend a product's shelf life might pose a disincentive to manufacturers. RADM Lushniak noted the issue is complex, but FDA is considering such questions in relation to Tamiflu.

Dr. Pavia recommended that the Board make pandemic flu preparation a priority, because it encompasses so many issues in common with other threats, such as questions about industry involvement, biosurveillance, and distribution. He said Board members have expertise in manufacturing pharmaceuticals, vaccine implementation, and development of diagnostics; he asked how the Board could help the most. Dr. Robinson responded that threatened budget cuts mean BARDA may have to redefine its top spending priorities rapidly. He explained that the loss of $800 million from the budget would virtually wipe out all planned spending for advanced vaccine and antiviral product development and stockpiling. Dr. Gerald Parker added that the Federal government had a strong upfront commitment from Congress and the Executive Branch to support pandemic flu research and development, but the budget cut would endanger the partnerships formed to support such efforts and damage commitment to strategic planning.

Dr. Grabenstein raised concerns about how often the seasonal flu vaccine does not match the actual flu strain, despite the best efforts of the FDA, CDC, and WHO. He called for a better, more durable vaccine. Dr. Robinson replied that the NIH is researching a so-called

universal vaccine, and BARDA will support such research when it advances. He said BARDA has funded research on adjuvants, which would be helpful in moving toward a universal vaccine.

Dr. John Parker asked whether any research has determined who should use masks to prevent the spread of disease: those who are sick or those who are not? Dr. Robinson said the issue needs further study, and research should also address whether masks can in fact filter out viruses as well as bacteria. He added that 95 percent of masks are manufactured overseas, and domestic production and stockpiling should be considered. Dr. Gellin noted that HHS is publishing "common sense guidance" on using masks and respiration devices because the science is too weak to support evidence-based recommendations. He suggested the Board consider examining the existing research on transmission and protection. Appropriate disposal of contaminated devices used to block transmission is another area of interest, Dr. Gellin said. RADM Lushniak pointed out that recommending a mask to prevent disease transmission makes the mask a medical device, subject to FDA regulation to determine efficacy. Dr. Pavia asked for an assessment of research evaluating these questions.

From the discussion, Dr. Quinlisk identified topics that should be addressed by a subcommittee on pandemic flu: manufacturing and stockpiling medications, flu vaccine mismatch, and devices for physical protection from disease transmission. Dr. James pointed out that many groups are looking at the same issues, and all have complained about the lack of research. He suggested the Board should take a broader approach, such as defining a uniform model for reviewing the science.

Mr. Di Rienzo asked whether the work of the American Health Information Community toward uniform health data collection could be leveraged to provide data for modeling. Dr. Gellin said this topic has been discussed with Dr. Robert Kolodner, National Coordinator, Health Information Technology. HHS; Dr. Gellin said a Board subcommittee could evaluate the data about flu gathered from existing immunization and adverse events registries.

Dr. John Parker and Dr. Scannon proposed a subcommittee to review the Federal research portfolio on threats and make recommendations on coordinating research efforts, particularly regarding countermeasures and biosurveillance.

Dr. James said HSPD-21, which focuses on disaster medicine, addresses most of the issues raised by the Board. He proposed a subcommittee that would work with the White House staff that developed HSPD-21 and ex officio Board members to define a unified model and identify the legal and regulatory obstacles to accomplishing such a model.

Ms. Carlin asked that special populations and at-risk individuals be considered part of the agenda for all the subcommittees and their needs reflected in any NBSB recommendations. Dr. Dodgen noted that ASPR is required to include at-risk individuals in all of its emergency preparedness efforts, so Ms. Carlin's suggestion dovetails with the government

requirements. He added that the Board is uniquely qualified to advise on development and deployment strategies of countermeasures for at-risk populations.

Mr. Di Rienzo said communication and data interoperability should also be part of all the subcommittees' deliberations and Board recommendations. He explained that interoperability conflicts occur when research data are presented in ways that do not allow for comparison with other research findings. Mr. Di Rienzo offered to assist subcommittees with evaluating and promoting data sharing. Dr. MacVittie agreed that experts in the field should be working to support better exchange of research data. Dr. Highnam pointed out that the Nationwide Health Information Network (an effort being shepherded by the Office of the National Coordinator for Health Information Technology, HHS) incorporates "use cases," or detailed scenarios to help address issues relevant to this discussion on interoperability, as well as to other specific topics of interest to the subcommittees.

Dr. John Parker wondered how to allay concerns that a subcommittee seeking to coordinate research efforts not be viewed as an attempt to eliminate any research efforts or create a new power center. Dr. Vanderwagen assured the Board that communication among agencies about research efforts is generally good, and it is appropriate to advise the Secretary of HHS on closing gaps in research. Dr. Linden said many meetings in the context of PHEMCE involve sharing program information across agencies, and efforts are made to avoid duplication of research investments. Dr. Scannon noted and Dr. Linden agreed that such efforts should be formalized so they are not lost when key people change jobs.

Dr. Hatchett suggested the Board consider some larger, overarching issues, such as gaps in infrastructure or development of a common vocabulary to enable communication about aspects of emergency preparedness, biodefense, etc.

Dr. Pavia suggested a subcommittee to address issues in the medical countermeasures marketplace, such as what drives innovation and how the government can sustain industry in medical countermeasure development. Board members concluded that such a subcommittee would focus on analyzing "external," or non-governmental factors, while another subcommittee would address government research efforts and gaps, and the two would eventually integrate.

Dr. James reiterated his call to use HSPD-21 as a framework for developing a national disaster medicine network that includes disaster medicine training and education.

Dr. Grabenstein pointed out that Congress directed that the Board includes four representatives from industry, so market considerations should be a topic of discussion. Dr. Rose agreed, adding that industry development of countermeasures is hampered by the uncertain nature and size of the marketplace. He said the public-private partnership to develop a marketplace for orphan drugs (i.e., drugs for very rare conditions) could be a model for countermeasures. Dr. Hatchett noted that the development of drugs for neglected diseases in developing countries is another model.

PUBLIC COMMENT

Chris Colwell of the Biotechnology Industry Organization (BIO) expressed his gratitude to HHS and its counterparts for establishing the Board and thanked the Board members for giving their time and energy to the effort. He said his organization believes incentives can succeed in promoting development of medical countermeasures among biotechnology companies. Mr. Colwell suggested that the Board not allow current funding constraints to limit thinking about what can and needs to be done.

NBSB ACTIONS AND NEXT STEPS

The Board reached consensus on the following working groups, their makeup and initial charges:

PANDEMIC FLU RESEARCH

Chair	Dr. Pavia
NBSB Members	Dr. Berkelman, Dr. Cantrill, Ms. Carlin, Dr. Grabenstein, Mr. Di Rienzo, Dr. Rose
Ex Officio Agency Representatives	Dr. Annelli, USDA; Dr. Linden, BARDA; RADM Lushniak, FDA
Mission and Issues to Consider	Evaluate the current research and identify gaps.
Product for Next NBSB Meeting	Inventory of the science, particularly the early science, with attention to budget issues, and possibly risk assessment

U.S. GOVERNMENT RESEARCH AND ADVANCED DEVELOPMENT PORTFOLIO ON CBRN AGENTS

Co-Chairs	Dr. Dretchen for biosurveillance , Dr. Scannon for medical countermeasures
NBSB Members	Dr. Berkelman, Dr. MacVittie, Dr. Parker
Ex Officio Agency Representatives	Dr. Auchincloss, NIH; Dr. Besser, CDC; Dr. Colby, White House Office of Science Technology and Policy; Dr. Linden, BARDA/ASPR; Dr. Noah, DHS
Mission and Issues to Consider	• Evaluate the current research and identify gaps. • Consider current efforts to integrate and collaborate across disciplines and agencies. • Determine whether successful collaboration/communication mechanisms can be institutionalized.

	• Consider how the current research efforts relate to questions of market sustainability and product development.
Product for Next NBSB Meeting	Review of status of HHS and DOD efforts at collaboration and integration of research; for biosurveillance, summary of government perspective on directions for future research

DISASTER MEDICINE

Chair	Dr. James
NBSB Members	Dr. Cantrill, Mr. Di Rienzo, Dr. Dretchen
Ex Officio Agency Representatives	Dr. Annelli, USDA; Dr. Besser, CDC; Dr. Deyton, Department of Veterans Affairs; Dr. Linden, BARDA/ASPR; Dr. Noah, DHS; ASPR, Dr. Staley, White House Homeland Security Council; and DOD
Mission and Issues to Consider	Use HSPD 21 as a framework for evaluating how to develop a national disaster medicine system and disaster medicine education and training that supports such a system.
Product for Next NBSB Meeting	Analysis of strengths, weaknesses, and opportunities of HSPD 21

GAPS IN THE MEDICAL COUNTERMEASURES MARKETPLACE

Chair	Dr. Parker
NBSB Members	Dr. Grabenstein, Dr. Pavia, Dr. MacVittie, Dr. Rose, Dr. Scannon
Ex Officio Agency Representatives	Dr. Auchincloss, NIH; Dr. Linden, BARDA/ASPR; RADM Lushniak, FDA; the Department of Commerce, and the DOD
Mission and Issues to Consider	Consider development of orphan drugs and drugs for neglected diseases in developing countries as models.
Product for Next NBSB Meeting	• Evaluation of findings of subcommittees on pandemic flu and CBRN research • Identification of top four gaps in the marketplace

The Board agreed on the following directives to guide the activities of the subcommittees:

- For all subcommittee deliberations, findings, and recommendations
  - address at-risk populations, as defined by PAHPA, or explicitly describe why they are not addressed, and
  - address communication and data interoperability or explicitly describe why they are not addressed.
- Review the list of topics for consideration that emerged from Board discussion on December 17 (see "Issues and Topics for NBSB Consideration, Part I" above) and consider whether any can be addressed by your subcommittee.
- Review the NBSB charge and take it into account during subcommittee deliberations.
- Present recommendations to the Board for review.

The Board approved the following logistic and administrative approaches to support the subcommittees and the Board:

- An NBSB staff member will be assigned to support each subcommittee.
- NBSB staff will convene a teleconference on administrative issues for subcommittees.
- Each subcommittee will present initial findings to the Board at the next Board meeting.
- If subcommittees identify background materials of interest to the Board, those materials should be submitted to NBSB staff approximately 1 month before the next NBSB meeting so they can be distributed to the Board members in advance of the meeting.
- NBSB staff will circulate Board members' e-mail addresses among the Board members.
- NBSB staff will develop the agenda for the next Board meeting on the basis of discussions with subcommittee chairs, allotting appropriate time for subcommittee presentations and Board discussion.

Board members agreed to a tentative date of June 4–5, 2008, for the next meeting. Dr. Quinlisk recommended ending by 3 p.m. on the second meeting day to allow people to catch evening flights home.

CLOSING REMARKS AND ADJOURNMENT
Patricia Quinlisk, M.D., M.P.H., Chair

Dr. Quinlisk thanked the Board members for their time and input and the NBSB staff for their work in facilitating the meeting. She adjourned the meeting at 5 p.m. Tuesday, December 18, 2007.